

Our Reference: UMJ-113-B (UM1992)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Peter X. Ma et al.  
Serial Number: 10/057, 287  
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Examiner/Art Group Unit: David M. Naff/1651  
Title: MICROTUBULAR MATERIALS AND  
MATERIAL/CELL CONSTRUCTS

DECLARATION PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Peter X. Ma, hereby declare the following:

1. I am a co-inventor of the above-identified application.
2. I am a citizen of the United States residing at 3208 Foxway Court, Ann Arbor, Michigan 48105.
3. I received a Bachelor of Science in Polymer Chemistry and a Master of Science in Polymer Materials from Tsinghua University in Beijing, China.
4. I received a Master of Science and a Ph.D in Polymer Science and Engineering from Rutgers University, New Brunswick, New Jersey, in 1993.
5. I performed post doctorate work at MIT in Cambridge, Massachusetts, from 1993-1996 in Biomaterials and Tissue Engineering.
6. I joined the University of Michigan in 1996 as a professor and have engaged in the research of polymeric biomaterials, tissue engineering, ion-containing polymers, and biomechanics since then. I have worked on development and structure-property relationship studies of polymer systems of biomedical importance, such as bioactive

polymer materials, biodegradable polymers and mechanically superior polymeric multiphase materials. Further, I have worked on understanding polymer-cell interactions, and the signal and substrate requirements for cell proliferation and tissue regeneration in three dimensions to create functional tissues. Regarding biomechanics, I have studied the biomechanical behavior of engineered tissues in relation to biochemical composition, morphology and function and the effects of mechanical stimulation on tissue regeneration on three-dimensional polymer scaffolds.

7. With R. Zhang, I performed the underlying research and wrote the paper entitled "Poly( $\alpha$ -hydroxyl acids)/hydroxyapatite porous composites for bone-tissue engineering. I. Preparation and morphology" dated 1999. Figure 1d as shown in the Zhang/Ma 1999 reference is different from the microtubular materials and material/cell constructs as disclosed and claimed in the above-identified U.S. Patent Application Serial No. 10/057,287.

8. As seen in the Zhang/Ma 1999 reference at page 449, the SEM micrograph is of a section of a PLLA foam made from 2.5% (w/v) PLLA/dioxane solution (quenching temperature:  $-18^{\circ}\text{C}$ ). Figure 1d shows the PLLA foam having a highly anisotropic tubular morphology with an internal ladder-like structure, with the channels being parallel to the direction of solidification.

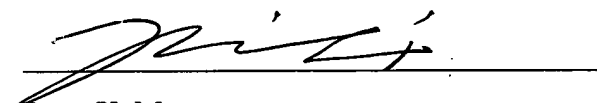
9. Exhibit 1 is a SEM of a section of a PLLA foam prepared from the 2.5% (w/v) PLLA/dioxane solution (quenching temperature:  $-18^{\circ}\text{C}$ ) (the same materials, solvent and conditions that formed the foam of Zhang/Ma Figure 1d).

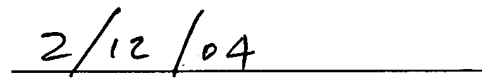
10. After reviewing Figure 1d of the Zhang/Ma 1999 reference and Exhibit 1, I submit that the substantially parallel oriented pores of Figure 1d are a portion of the entire PLLA foam. Other portions of that foam were also locally oriented, but not parallel to the portion shown in Figure 1d. Still other portions were randomly oriented, similar to that shown in Exhibit 1. Exhibit 1 is a portion of a foam (formed from the same materials and in the same manner as the foam shown in Zhang/Ma Figure 1d) illustrating that the pores are not parallel, but rather have a random orientation.

11. Comparing the two figures, I submit that substantially the entire PLLA foam of the Zhang/Ma 1999 reference does not have a uniform, parallel microtubular structure as does the Applicants' invention as claimed in U.S. Patent Application Serial No.

10/057,287. As seen in Exhibit 1, the orientation of the pores is random rather than substantially parallel. From this Exhibit, it is submitted that Figure 1d of the Zhang/Ma 1999 reference does not form "microtubular polymeric materials comprising a plurality of microtubules having a predetermined architecture with each of the plurality of microtubules arranged substantially parallel to each other, substantially uniformly throughout the materials" as defined in the claims in the above-identified application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and, that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

  
Peter X. Ma

  
Date

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**Exhibit 1**

